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10/786,053	02/26/2004	Kazumichi Imai	29273/317	3303

7590
KENYON & KENYON
Suite 700
1500 K Street, N.W.
Washington, DC 20005

10/04/2007

EXAMINER

OLSEN, KAJ K

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1795

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/786,053

Applicant(s)

IMAI ET AL.

Examiner

Kaj K. Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/132,323.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2-26-2004.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: In the specification amendment of 2/26/2004, applicant should indicate that application no. 09/852,269 has since matured into USP 6,740,219.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In claims 1 and 9, it is unclear whether applicant is actually claiming a sample tray. In particular, claims 1 and 9 only explicitly define a presence of a sample tray holder "capable of removably fixing a sample tray" implying that the sample tray is not itself being claimed. However, later in the same claims and in the numerous dependent claims, applicant further define features of the sample tray itself implying that the sample is indeed part of the claimed invention. For the purpose of examination, the examiner will presume that claims 1 and 9 are explicitly reciting the presence of a sample tray, but clarification is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kernan et al (USP 5,885,430).

7. Kernan discloses an electrophoretic apparatus comprising a plurality of migration passages 32, a sample tray holder 206 capable of removably fixing a sample tray 64 that includes a plurality of sample vessels for containing samples (col. 4, ll. 30-36), a detector for optically detecting sample components separated by electrophoresis (col. 4, ll. 26-29), a power supply (72, 414) for applying voltage to the migration passages (col. 4, ll. 52-62). With respect to the limitation requiring the sample tray comprise an electrode capable of contacting the sample, Kernan appears to disclose two means for establishing electrical connection to the sample. One is to have the electrode leads 74 somehow extend either through or around the sample tray 64 to establish the electrical connection. See fig. 1 and col. 4, ll. 52-62. Another is to establish electrical connection via a plate 172 on the cartridge 80 of the device. See fig. 3B and 4 and col. 7, l. 17 through col. 8, l. 3. Both of these examples would read on "said sample tray comprises an electrode", giving the claim language its broadest reasonable interpretation, because the sample tray would have an electrode either placed through on in the sample tray. With respect to part of the sample tray holder being electrically connected to the power supply, the examiner

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notes that the embodiment of fig. 1 shows the electrodes leads 74 extending through the sample tray from below the sample tray. Because the sample tray holder of Kernan would also be below the sample tray as well in the same position occupied by leads 74 in fig. 1, one possessing ordinary skill in the art would have been motivated to utilize a portion of the sample tray holder as an electrical connection because the sample tray holder occupies the intermediate space between the power supply and microtiter plate. For example in fig. 10, the power supply 414 is located below the sample tray holder mechanism (446, 448). In order to establish the electrical connections shown in fig. 1, the most direct path for the electrode leads would be through the sample tray holder itself.

8. With respect to the use of stainless steel for the electrode, see col. 6, ll. 2-6.

9. Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kernan in view of Gardell et al (USP 4,628,026).

10. Kernan discloses all the limitations of the claims, but did not explicitly recite that the sample vessel is transparent. The sample vessel of Kernan is a microtiter tray and Gardell teaches that microtiter trays are conventionally constructed of transparent material. See col. 3, ll. 58-60. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Gardell for the apparatus of Kernan so that the contents of the sample vessel can be visually monitored.

11. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kernan in view of Karger et al (USP 4,997,537).

12. Kernan set forth all the limitations of the claims, but did not explicitly recite the use of a current detection circuit. Karger urges that regularly checking gel filled capillaries by measuring

the current through them to ensure that the capillaries are in good condition. See col. 12, ll. 47-58. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Karger for the apparatus of Kernan so as to ensure the capillaries are in good working condition.

13. Claims 8 and 16 (and claims 1, 3, 9, and 11 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Kernan in view of Kambara et al (USP 5,730,850).

14. With respect to claims 8 and 16, Kernan set forth all the limitations and appeared to set forth the wire going through the bottom portion of the microtiter tray 64. See fig. 1. However, Kernan didn't explicitly describe doing so. Hence to the applicant's benefit, the examiner will interpret Kernan as not anticipating this particular feature of claims 8 and 16. However, Kambara explicitly shows what Kernan merely hinted at and showed the electrode wire 13 going through the bottom of the microtiter tray 7 to establish electrode connection. See fig. 2a and col. 5, ll. 40-46. Kambara also shows in fig. 2a that a microtiter plate an upper portion having a plurality of openings and a base portion below this upper portion. Although the upper portion and base portion of Kambara are integral components, there is nothing in the claims that require these two portions to be physically separable entities. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Kambara for the apparatus of Kernan because Kambara explicitly demonstrates how the electrode can be embedded in each of the sample vessels to achieve appropriate electrophoretic contact.

15. With respect to claims 1, 3, 9, and 11 in the alternative, even if Kernan fig. 1 is not interpreted as providing support for having the electrode leads 74 extend from and through the

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sample vessel from below, then Kambara explicitly demonstrates how this is done and this feature would have been obvious over the further teaching of Kambara as discussed in the preceding paragraph. Furthermore as discussed above, because the electrode leads would be extending from the same location as the sample tray holder (compare fig. 2a of Kambara with fig. 10 of Kernan), it would have been obvious to one of ordinary skill in the art to utilize a portion of the sample tray holder as an electrical connection to the electrodes because the most direct path for the leads would be through the sample tray holder itself.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,740,219. Although the conflicting claims are not identical, they are not patentably distinct from each other because

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claim 1 of the instant invention and claim 1 of the patent appear to be identical except the patent claim includes the addition limitation "wherein said part of the sample tray holder is electrically connected to said electrode in response to fixing the sample tray to said sample tray holder".

Hence, claim 1 of the instant invention fully encompasses the claim 1 of the patent. Claims 2-8 of the instant invention appear to be identical in scope to claims 2-8 of the patent. Claim 9 of the instant invention appears to be identical in scope to claim 1 of the patent except that claim 9 also doesn't have the above additional limitation from the patent and claim 9 only specifies a single migration passage and a single sample vessel. However, because claim 9 has been constructed with open language (i.e. "comprising") and could comprise more than one migration passage and more than one sample vessel, claim 9 also fully encompasses claim 1 of the patent. Claims 10-16 of the instant invention also appear to be identical in scope to claims 2-8 of the patent.

18. Claims 1-3, 5-11, and 13-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 12 of U.S. Patent No. 6,325,908 in view of Kernan.

19. Claim 1 of the patent sets forth all of the limitations of claims 1 and 9 of the instant invention, but doesn't specify the presence of a sample tray holder removably fixing the sample tray, and a power supply for applying voltage to the passages. However as discussed above, Kernan disclose the use of a sample tray holder for holding and moving the sample tray to the capillaries for electrophoresis. Furthermore a power supply is necessary for the electrophoresis itself. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teachings of Kernan for the claimed invention of the patent so as to allow the sample tray to be held and moved to the capillaries so as to initiate the electrophoresis.

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With respect to part of the sample tray holder being electrically connected to the power supply, because the sample tray holder is placed below the sample tray (see Kernan) and because the claimed invention relies on the base of the sample tray as an electrode (see claims 1 and 2 as an example), it would have been obvious to one of ordinary skill in the art at the time the invention was being made to have part of the electrical connection go through the sample tray holder because the most direct path for the leads would be through the sample tray holder itself. With respect to the additional limitations present in claim 1 of the patent that are not in claims 1 and 9 of the instant invention, claims 1 and 9 of the instant invention fully encompass these limitations from the patent.

20. With respect to claims 2 and 10 of the instant invention, see claims 3 or 4 of the patent.

21. With respect to claims 3 and 11 of the instant invention, see discussion of Kernan and these claims above.

22. With respect to claims 5, 6, 11 and 12 of the instant invention, see claims 1 and 2 of the patent.

23. With respect to claims 7 and 13 of the instant invention, see claim 5 of the patent.

24. With respect to claims 8 and 14, see claim 12 of the patent.

25. Claims 4 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,325,908 in view of Kernan as set forth above and in further view of Karger.

26. These claims are further obvious over the teaching of Karger for the reasons set forth above.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
September 28, 2007


KAJ K. OLSEN
PRIMARY EXAMINER